DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Bio-Med USA Inc.
Mr. Young Chi
President
27 New England Drive
Ramsey, NJ 07446

Re: K142332
Trade/Device Name: BT-400 Neonatal Phototherapy
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: February 9, 2015
Received: February 18, 2015

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use statement

510 (K) Number : K142332

Device Name : BT-400 Neonatal Phototherapy

Indication for use : BT-400 is the Phototherapy unit intended for the treatment of Neonatal Hyperbilirubinemia caused by Indirect Hyperbilirubinemia.

Prescription use_____**XX**_____ or/and Over the Counter use_____
(Part CFR 801 sub part D) (Part 21CFR 801 Sub part C)

Please do not write below line- continued an another pages if needed

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Concurrence of CDRH office of ODE

510 (K) Summary

As required by CFR 807.92(c)

1. Manufacturer

Revised Mar 18,2015

Bistos Co Ltd. Reg Nr: 3005179052
7th fl, A bldg WooLim Lions Valley,
302 Galmachi ro, JungWon gu, Seoung Nam, GeongGi, Rep of Korea
t: 82 31 750 0340 f: 82 31 750 0344

2. Applicant and Contact person

Bio-Med USA Inc.
Young Chi, President.
27 New England Drive, Ramsey, NJ 07446. U.S.A.
t: 1-973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	BT-400 Neonatal Phototherapy
Classification name :	:	Unit, Neonatal Phototherapy
Common name	:	Neonatal Phototherapy
Regulation	:	880.5700 Class II
Classification Panel	:	General Hospital.
Product Code	:	LBI

4. Legally marketed Predicate Device

K103828 Atom Medical Corp, Japan BILI-THERAPY Spot type.

5. Device Description

BT-400 Neonatal phototherapy is designed to emit the blue light wave length range 450-470nm spectrum to treat Neonatal Jaundice to use in Bassinets, Incubators, Open beds or Radiant warmer and consists of

Head (Light Source)
Control box with LCD window
Roll Stand (optional)

6. Intended use

BT-400 Phototherapy unit is intended for the treatment of Neonatal Hyperbilinemia caused by indirect Hyperbilinemia.

7. Performance Data

Performed below listed Bench Tests, and all data met cited standard required criteria.

IEC60601-1 Medical Electrical Equipment :2006
part 1 : General requirements for basic safety and essential performance.

IEC 60601-1-2:2007 Electromagnetic compatibility test

IEC60601-2-50 Medical Electrical Equipment
part 2-50: Particular requirements for the basic safety and essential performance of Infant Phototherapy Equipment

The Device is non contacted mode.

8.Technological Characteristics .

BT-400 Phototherapy is light emitting Blue LED (Light Emitting Diode) to treat Neonatal Hyperbilirubinemia in the range of 450-475 nm wave length, which are considering most effective for the degradation of Bilirubin.

The The BT-400 Phototherapy and the predicate device are phototherapy units intended to treat neonatal hyperbilirubinemia. The wavelength and intensity of blue light utilized is comparable between the two devices. Operational and functional parameters between the two devices are also highly similar. Both devices are in compliance with the applicable IEC 60601 standards.

Note performance is similar since subject device intensity is few microwatts higher and effective area is slightly large compared to the predicate device.

Comparison to Predicate Device

Feather	**Proposed Device**	**Predicate Device**
	Bistos Co., Ltd BT-400 Model BT-400	**Atom Medical Corp** Model : BILI-THERAPY spot type K103828
Light Source	Blue LEDs	Blue LEDs
Wavelength	Peak 450-475nm	Peak 450-475nm
Intensity	30-45uW/cm2 at 30cm distance	30-40uW cm2 at 30cm distance
Variation in intensity in 6 hrs	+_ 10% in Illumination area	Identical
Effective Surface	40x20cm	30x20cm
Head output over 6 hrs	<10'c warmer than ambient	Identical

Electrical Main power	100-120v ac 50/60 hz 70va	Identical
Safety		
Leakage current	<100uA	Identical
Audible Noise	<60dB	Identical
Dimension		
Maximum height	200cm	190cm
Header	340x210x750mm	320x200x700mm
Weight	12 kg	Identical
Light assembly / Roll Stand	3.6kg / 8.4kg	
Environmental		
Operating Temp/Humidity	10-40'C / 30-75%	10-30'C / 30-85%
Storage Temp / Humidity	0-50'C / 10-100%	0-45'C / 10-90%
Atmospheric Pressure	70 kPa-106 kPa	Identical
Regulatory Standard	EN6001-1, EN60601-1-2 EN60601-2-50	Identical
Intended use		
	BT-400 is a phototherapy units intended for the treatment of Neonatal Hyperbilirubinemia caused by indirect Hyperbilirubinemia.	BILI-THERAPHY is a phototherapy units intended for the treatment of Neonatal Hyperbilirubinema. .

9. Conclusion.

The BT-400 Neonatal Phototherapy is substantially equivalent to the predicate BILI-THERAPY Spot type (K103828) in indication for use, patient population, and environment for use, technical characteristics, specifications/ performance and compliance with international standards.